

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

SAREPTA THERAPEUTICS, INC. and THE  
UNIVERSITY OF WESTERN AUSTRALIA,

Defendant/Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD.  
and NS PHARMA, INC.

Plaintiff/Counter-Defendants.

C.A. No. 21-1015 (GBW)

REDACTED - PUBLIC VERSION

**DEFENDANTS' OPENING LETTER BRIEF TO THE  
HONORABLE GREGORY B. WILLIAMS IN SUPPORT OF THEIR  
MOTION TO STRIKE DR. MATTHEW WOOD'S EXPERT REPORTS**

Dear Judge Williams:

On August 3, 2023, Defendant Sarepta Therapeutics, Inc. (“Sarepta”) moved to exclude Dr. Matthew Wood from serving as an expert for Nippon Shinyaku (“NS”) [REDACTED] (D.I. 298). The Court has not yet ruled on that motion. While Sarepta’s motion has been pending, NS submitted three expert reports from Dr. Wood (Exs. 1-3), and Sarepta took his deposition. In view of the information provided in Dr. Wood’s expert reports and the testimony provided at his deposition, Sarepta hereby moves to strike Dr. Wood’s expert reports. The bases for this motion also provide further support for Sarepta’s August 3, 2023 motion to exclude Dr. Wood.

As summarized in Sarepta’s August 3rd motion, [REDACTED]

[REDACTED] Dr. Wood also provided extensive opinions supporting the validity of patents related to the Wilton patents being asserted by Sarepta and UWA in this case [REDACTED]

[REDACTED] Sarepta moved to disqualify Dr. Wood. In that motion, as well as in Sarepta’s opposition to NS’s motion to disclose confidential information to Dr. Wood, Sarepta identified a significant risk of prejudice should Dr. Wood serve as an expert witness for NS. (D.I. 298 at 1). This has since been proven to be the case—the substantial risk of prejudice that Sarepta identified during the briefing of the earlier motions has now materialized, as evidenced by, for example, Dr. Wood’s Reply Report and deposition testimony.

First, during the earlier briefing, Dr. Wood submitted a sworn declaration to the Court certifying that he “will not be offering opinions concerning the infringement or validity of U.S. Patent Nos. 9,994,851, 10,227,590 or 10,266,827, which I understand are the patents being asserted by Sarepta and UWA.” (D.I. 309, ¶ 3). Despite this declaration, and despite previously opining as to the *validity* of other patents in this same family, Dr. Wood now provides opinions in his reports directly evaluating whether the Wilton Patents (i.e., the ’851, ’590 and ’827 Patents) satisfy the written description requirement—a *validity* requirement. For example, in his Reply Report, Dr. Wood opines that “a POSA reviewing the UWA Specification upon its publication as Wilton PCT ’057 would not have understood the inventors to have *discovered, possessed, recognized, or appreciated* any general properties of exon 53 skipping AONs that alleviated or resolved the unpredictable nature of designing such AONs to induce exon 53 skipping, much less *the structural characteristics recited in the claims filed in the 2017 application that issued as the ’851 Patent*” (¶ 14) and that “a POSA would have concluded that the inventors possessed only the

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<sup>1</sup> “Evans Decl.” refers to the Declaration of Marc D. Evans submitted with Sarepta’s opening letter regarding its motion to exclude Dr. Wood as an expert witness (D.I. 299-0).



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AONs disclosed in the UWA Specification” (Ex. 3 at § II.C). That opinion expressly contradicts Dr. Wood’s representation to this Court that he would not provide opinions regarding the validity or invalidity of the Wilton Patents; indeed, his opinions regarding “possession” of the subject matter of the claimed invention, including “structural characteristics,” directly implicate compliance with the written description requirement of 35 U.S.C. § 112. *See, e.g., Pandrol USA, LP v. Airboss Ry. Prods., Inc.*, 424 F.3d 1161, 1165 (Fed. Cir. 2005) (“Compliance with § 112 requires sufficient information in the specification to show that the inventor *possessed* the invention at the time of that original disclosure. The possession test requires assessment from *the viewpoint of one of skill in the art.*” (internal citations omitted) (emphases added)); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc) (“[A] sufficient description of a genus instead requires the disclosure of either a representative number of species falling within the scope of the genus or *structural features common* to the members of the genus.” (emphasis added)).<sup>2</sup>

Dr. Wood’s deposition testimony further demonstrates that neither he nor Sarepta can ensure that NS will avoid the improper use of Dr. Wood’s testimony. Dr. Wood acknowledged that the discussion in his Reply Report regarding [REDACTED]

Wood Tr. at 141:25-143:4 (Ex. 4). Dr. Wood testified that

(*id.* at

147:9-20),

It is clear from his deposition testimony that Dr. Wood does not and cannot know how NS will use his testimony at trial or in briefing. But it is clear from his reports and testimony that NS intends to offer it in support of NS’s invalidity theories.

Dr. Wood’s expert reports and deposition testimony highlight the prejudice Sarepta will face if Dr. Wood’s reports are not stricken and if Dr. Wood is permitted to serve as an expert for NS in this case, including prejudice resulting from his “switching sides” and from the risk of disclosure to NS of Sarepta’s confidential information previously provided to Dr. Wood. *See* D.I. 298 at 2-3. Dr. Wood’s reports and testimony also demonstrate that the assurances Dr. Wood and NS provided during its briefing are hollow promises.

For the reasons set forth herein, and in Sarepta’s earlier letters, Sarepta respectfully requests that the Court strike his expert reports and disqualify Dr. Wood from serving as an expert for NS.

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<sup>2</sup> During the parties’ meet-and-confer, NS’s counsel offered to strike the word “possessed” from Dr. Wood’s reports. But that would not solve the problem with Dr. Wood’s reports, as they would still permit him to opine regarding a POSA’s understanding of the disclosure of the specification and whether it conveyed the general properties of exon 53 skipping AONs or the structural features of the claimed invention—issues directly pertinent to the § 112 analysis.

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Respectfully,

*/s/ Megan E. Dellinger*

Megan E. Dellinger (#5739)

MED/bac

Attachments

cc: Clerk of the Court (via hand delivery; w/attachments)  
All Counsel of Record (via electronic mail; w/attachments)